TRANSCRIPT OF PROCEEDINGS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DENTAL PRODUCTS PANEL

of the

MEDICAL DEVICE ADVISORY COMMITTEE

OPEN SESSION

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Pages 1 thru 273

Rockville, Maryland
October 6, 2000

MILLER REPORTING COMPANY, INC.
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AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DENTAL PRODUCTS PANEL

of the

MEDICAL DEVICE ADVISORY COMMITTEE

OPEN SESSION

Friday, October 6, 2000

9 o'clock a.m.

Room 020B
9200 Corporate Boulevard
Rockville, Maryland

MILLER REPORTING COMPANY, INC.
735 8th Street, S.E.
Washington, D.C. 20003-2802

PARTICIPANTS

Leslie Heffez, D.M.D., M.S. Chairperson
Pamela D. Scott, Executive Secretary

MEMBERS

Kristi Anseth, Ph.D.
Edmond Hewlett, D.D.S.
Janine E. Janosky, Ph.D.
Mark R. Patters, D.D.S., Ph.D.

CONSUMER REPRESENTATIVE

Lynn Morris

INDUSTRY REPRESENTATIVE

Floyd Larson

PATIENT REPRESENTATIVE

Sue Warman

CONSULTANTS

Peter Bertrand, D.D.S.
Marcus Besser, Ph.D.
Richard Burton, D.D.S.
David Cochran, D.D.S., Ph.D.
Willie Stephens, D.D.S.

FDA

Timothy Ulatowski

C O N T E N T S

P R O C E E D I N G S

Welcome and Introductory Remarks

MS. SCOTT: Welcome to the meeting for the Dental Products Panel. To start off the meeting, I would like to introduce our panel for today.

Our chair for today's meeting is Dr. Leslie Heffez. He is Professor and Department Head of Oral and Maxillofacial Surgery with the University of Illinois at Chicago.

We also have with us today Dr. Kristi Anseth. She is Patten Associate Professor in the Department of Chemical Engineering at the University of Colorado.

We also have Dr. Edmond Hewlett. He is Associate Professor with the Division of Cariology and Restorative Dentistry with the University of California at Los Angeles, in the School of Dentistry.

We also have Dr. Janine Janosky. She is Assistant Professor with the Department of Family Medicine and Clinical Epidemiology within the School of Medicine at the University of Pittsburgh.

We have Dr. Mark Patters, who is Chair of the Department of Periodontology within the College of Dentistry at the University of Tennessee.

Our consumer representative for today is Ms. Lynn Morris. She is Deputy Director of the Board of Relations

with the California Department of Consumer Affairs, Executive Office.

Our industry representative is Mr. Floyd Larson. He is President of PacMed International. I have to apologize for the mistake in the program; it states Pacific Materials and Interfaces.

MR. LARSON: Former name; same thing.

MS. SCOTT: Former name; same company. Our patient representative today is Ms. Sue Warman. She is a TMJ patient, with past experience as a patient. Also, in the mid-80's she was the head for a local TMJ support group for about two years.

We also have with us today Dr. Peter Bertrand. He is the Director of the Orofacial Pain Clinic and specialty adviser for oral facial pain and TMD with the National Naval Medical Center.

We also have Dr. Marcus Besser, who is Assistant Professor in the Department of Physical Therapy at Thomas Jefferson University.

Also on our panel today is Dr. Richard Burton. He is Assistant Professor of Oral and Maxillofacial Surgery with the Department of Hospital Dentistry at the University of Iowa Hospitals and Clinics.

We also have Dr. David Cochran, who is Professor and Chair of the Department of Periodontics at the

University of Texas Health Science Center at San Antonio.

Also, we have Dr. Willie Stephens. He is Associate Surgeon for the Harvard Oral and Maxillofacial Surgery Associates.

Our FDA participants for today include Mr. Tim Ulatowski, who is the Director of the Division of Dental, Infection Control and General Hospital Devices. Also, we have Dr. Susan Runner, the Branch Chief for the Dental Devices Branch; and Ms. Angela Blackwell who is a reviewer within the Dental Devices Branch.

Before we get into the meeting, I have several administrative items to take care of. The first is the reading of the conflict of interest statement for today's meeting.

The following announcement addresses conflict of interest issues associated with this meeting, and is made part of the record to preclude even the appearance of an impropriety.

The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interest. To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. The agency has determined that no conflicts exist. However, we would like to note for the

record that the agency took into consideration a matter regarding Dr. Willie Stephens who reported interest but no financial involvement in firms at issue. The agency has determined that Dr. Stephens may participate fully in all deliberations.

In the event that the discussions involve any other products of firms not already on the agenda for which an FDA participant has a financial interest, the participant should excuse him or herself from such involvement and the exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products they may wish to comment upon.

The second item that I need to read into the record is our appointment to temporary voting status. Pursuant to the authority granted under the Medical Devices Advisory Committee charter, dated October 22nd, 1990, as amended April 20th, 1995, I appoint the following people as voting members of the Dental Products Panel for this panel meeting, on October 6th, 2000, Dr. Peter Bertrand, Dr. Richard Burton, Dr. Marcus Besser and Dr. Willie Stephens. For the record, these people are special government employees and are consultants to this panel under the

Medical Devices Advisory Committee. They have undergone the customary conflict of interest review. They have reviewed the material to be considered at this meeting. Signed, Dr. David Feigal, Director for the Center for Devices and Radiological Health, October 2nd, 2000.

At this time, I would like to turn the meeting over to our Chair, Dr. Leslie Heffez.

DR. HEFFEZ: I want to welcome everyone to the meeting. I would like to hold this open public hearing in an organized fashion. In order to do this, we have a number of presenters and I will ask each presenter to stick to a time limit of five minutes. If it appears that you are going to extend beyond the five minutes I will give you a little warning and interrupt your presentation. Prior to your presentation, I would like you to restate your name. I would like you to state if there is any financial interest present regarding your presentation and yourself and, in particular, if your attendance currently, today, is supported by a company or other.

Without further ado, I would like to start the public hearing and ask Antoinette Hosford to present.

Open Public Hearing

MS. HOSFORD: My name is Antoinette Hosford. I have no financial stake in the company.

In about 1989, I began to have three to four

migraines a month and my jaw would pop really loudly across the room. Then I began to have severe constant pain in my jaw all the time. Finally, after the third or fourth visit to my family doctor, telling him about the migraines and the pain, I was referred to a neurosurgeon who then referred me back to my family doctor and said I had no brain problems, who then ordered an x-ray and an MRI of my jaw and determined that I had problems with my TM joint.

I was sent to a dentist who tried several different programs to help me without doing surgery. We tried to splint. We tried medication. Eating with the splint, I had no relief in pain. It just gradually got worse and I could not eat hardly anything, except soft food and just liquid things.

We were then referred back to my oral surgeon who advised me and counseled me on having surgery with the Christensen implant. I had the surgery April 15th, 1992 and for eight and a half years have had no problem whatsoever with my jaw. I have the Fossa, the partial implant, and have just been really pleased with it. I have a friend who had two different surgeries. They were unsuccessful and I know that she is now trying to have the Christensen implant, and hopes that that will give her relief. Her husband had advised me not to have the surgery but we went ahead with it.

And, I am just here to let you know that I think the Christensen Fossa implant is wonderful. This is the only surgery that I have ever had. I have never had any other surgery before or after. We did try the splint and medication but they didn't seem to help at all. I couldn't open my jaw; I had migraines. Since I have had the surgery I have been really pleased with it, and I don't know where I would have been had I not had the surgery the first time. I might have had several other surgeries until coming upon the Christensen implant and I am very pleased that that was the first and only surgery that I have ever had.

DR. HEFFEZ: Thank you. Just for the record, was your attendance supported by the company?

MS. HOSFORD: No.

DR. HEFFEZ: Okay. The next speaker will be Charlene Jaspersen.

MS. JASPERSEN: Good morning, panel. My name is Charlene Jaspersen, and I do not have any financial interest in the company.

I am here in support of the Christensen Fossa-Eminence prosthesis. My story began several years ago. I suffered with TMJ for about fifteen years. I tried all of the conservative treatments, soft food diets, pain meds, muscle relaxants, tranquilizers, splints and three arthroscopic surgeries that did not work for me. I was

given a non-chew cookbook and told there is nothing else that can be done for me.

Then, I was given a "don't" list, and that consisted of: Don't chew gum. Don't eat hard or chewy foods. Don't clench down on your teeth. Don't sing or talk for any long periods of time. Do not do vigorous exercise. Don't chew on fingernails, pencils, bobby pins, and so forth." Don't yell or open mouth wide. Don't drink through a straw. Don't smoke. Don't carry heavy bags, purse and so forth.

My "do" list was: Do support your lower jaw when yawning. Do apply hot and cold compresses on the jaw. Do eat a soft diet and cut food very small. Do try to avoid stressful situations and get a good night's sleep.

None of these procedures relieved my pain and suffering from this debilitating disease. I was even told to learn how to live with it and make the best of it. I could not eat, smile, talk, laugh or even have my teeth worked on. Kissing my husband was such an effort and caused me so much pain. I lived on a diet of baby food, soups, mashed potatoes and so forth.

My family and friends had had enough of the pain and suffering I was going through. I was even giving up on life. I knew then it was time to find some answers to this TMJ pain that I was living with, and the doctor I was seeing

at that time told me I need not come back to him anymore if I had found another procedure.

I heard of the Christensen implant from a friend of mine. I then made an appointment to meet with a doctor who specialized in TMJ treatments to see if I was a good candidate for the prosthesis. In December of 1990 I had the Christensen Fossa-Eminence prosthesis implanted bilateral in place of my disk that had badly deteriorated with the rheumatoid arthritis. I am now ten and a half years postop and doing great, with no pain in the TM area. I am eating everything I want, including steaks and hamburgers, sub sandwiches. I can even eat hard candy. I have no restrictions or limitations, and I can smile and have my teeth worked on without any problems, and without my jaw locking either open or closed. I am living a normal life and I sometimes forget that I ever had TMJ.

In May of 1990 I had a CT scan on my jaws. My implants, the Fossa-Eminence prosthesis, looks as good as the day they were implanted. There are no loose screws on the implants and they are still in place in the disk area. My own condyles were not replaced at the time of the Fossa-Eminence implant in December of 1990. My condyles showed a slight deterioration from the rheumatoid arthritis at the time. To this date, my own condyles still look great and, in fact, they do look better than before and do not need to

be replaced. The Fossa-Eminence prosthesis has done the job and stopped the process of deterioration to my condyles.

I feel very fortunate that I have the Christensen implant as I have friends that have other types of implants, like the Vitek and Silastic and Teflon Proplast. They have caused them so much damage to their TM joint, along with pain and suffering. The Christensen implant, the Fossa-Eminence prosthesis has given me back my life. I have not had to have many multiple surgeries and I feel normal once again.

In closing, I would like to say I don't know where I would be today if it had not been for the Christensen Fossa-Eminence. I feel truly blessed. Thank you.

DR. HEFFEZ: Thank you. Miss Jaspersen, and for others who are going to present, there is a slight difference between someone having no financial interest and whether your attendance was supported.

MS. JASPERSEN: My attendance was not supported.

DR. HEFFEZ: Thank you. And, future presenters, please address those three issues. The next presenter is Ellen Lucus.

MS. LUCUS: My name is Ellen Lucus, and I have no financial or involvement with any other joint. You are looking at a three-time failure. Three failed total jaw joints. I know this meeting is about the all-metal

Christensen joint but I would like you to humor me as I discuss all three of my failed joints.

First, there was the Vitek VKII, and I feel the need to express to you my extreme disappointment in the way you, the FDA, has handled this failure. You allowed these joints on the market without strict safety guidelines. Then, when you discovered the horrible problems with Vitek you covered your butts by "grandfathering" in the rest of the joints instead of thoroughly checking the safety of these joints. If you had checked out these joints back in '91 and '92, we wouldn't be here right now discussing the all-metal joint problems.

Also, there are many people still out there that don't know that the joints in their heads have been recalled, and I know this for a fact because I have had to tell six people their joints were recalled over eight years ago, instead of the doctor telling them, and that is not fair to them or me. All you required of Amos is that they inform their patients and you haven't enforced that.

Now I would like to address the acrylic head Christensen. Whatever happened to this joint? It mysteriously went off the market. From what I can gather, around '93, '94, Dr. Christensen no longer provided these joints to doctors. Should I assume that he recognizes the problems with this joint? First he says there haven't been

wear problems with the condylar heads, but during the May 11th panel sessions he admits that they wear down, but this somehow makes them better. I would like to know what is the FDA's position on this joint, and if they are considered to be bad is there anything official from FDA stating this and if there isn't, why isn't there?

Now I would like to discuss the all-metal Christensen joints. I want to know why this joint was even allowed on the market to begin with. Around '93 or '94, Dr. Christensen started replacing the acrylic head joints with the all-metal. He told the FDA they have been on the market for, I think, around thirty years. Where is the data to prove this? And, if there is any proof, then they were introduced after you grandfathered the existing joints in. I want to know what type of testing you have done to justify that this is a safe joint.

My metal Christensen caused immediate pain and swelling. This pain and swelling got so bad that the joints had to be removed last July. My op reports, which I mailed to you with my Medwatch form, says that these joints caused metalosis. If you did a thorough job of testing these joints, why was I never asked to submit my joints to you for testing?

I would like to know more about the green material that has been oozing out of some of thee joints. Has it

ever been identified and, if so, what is it? And what kind of damage to my body should I expect from this?

We, the public, can't afford to have another medical catastrophe caused by a bad jaw joint, especially since we see how poorly you have helped us after Proplast. If my husband performed his job as well as some of you have performed yours he probably would have been fired by now, and you guys probably make a lot more than he does.

I am asking you to do your job based on thorough research, not pressure from big business. If these joints are allowed back on the market without proof to me that they are safe, I will be forced to put my op pathology and a copy of my Medwatch out there on the web for anyone who would like to see it.

Dr. Christensen and you, the FDA, were aware of the problems with metalosis and this joint, just from what I have submitted to you. And, I would like to make one last comment. Every once in a while I get really hard on myself for foolishly allowing three bad joints to be put in me, and it dawned on me that I keep giving you, the FDA, the benefit of the doubt that you are looking out for me but you keep letting me down, and all I am asking is that you don't let me down again. Thank you very much.

DR. HEFFEZ: Ms. Lucus, I will invite you to come back again. You are listed twice, for Sue Schweikert.

MS. LUCUS: I will just say it right now, Sue is a friend of mine and she can't be here right now because she is in real bad condition right now. Her teeth are crumbling. She has had the all-metal. Like I said, she is in such a bad position that she can't attend right now. Thank you.

DR. HEFFEZ: Thank you. Our next speaker will be Terrie Cowley.

MS. COWLEY: Good morning. In 1992 I made my first visit to Congressman Ted Weiss's office --

DR. HEFFEZ: Excuse me, just restate your name for the record.

MS. COWLEY: Terrie Cowley, and I have no financial interests in any company. In 1992 I made my first visit to Congressman Ted Weiss's office to describe to his legislative staffer what I knew about the Vitek and Silastic implants. She asked me what I knew about other devices on the market and when I said, "not much," she admonished me by saying, "if you are going to be a patient advocate, you darn well better know everything about every device out there." That meeting led to the congressional hearings called, "Are the FDA and NIH Ignoring the Dangers of TMJ Implants?" and the subsequent initiation of the classification process of these devices.

In the eight years since that congressional visit,

I have made it my business to learn as much as I can about all TMJ devices. This has been facilitated because the TMJ Association has become the 911 for most patients. From the May, 1999 Dental Products Panel meeting I learned the following about the Christensen models: First, the testing data on all Christensen devices were woefully inadequate. The May, 1990 panel went on to say that evaluation of TMJ Implants clinical data was impossible as all Christensen products were blended into one reservoir of anecdotal, case study, and retrospective data, a body of haphazardly collected information without the benefit of a clinical trial protocol. Over 80 percent of the patients were lost to follow-up.

Regarding the devices under discussion today, the TMJ Association has heard the following problems from patients: When the Fossa-Eminence prosthesis is used, the patient suffers what surgeons refer to as condyle "shredding" or degeneration, as well as Fossa-Eminence prosthesis fracture. Of the all-metal total joint, the primary complaints we hear are metalosis, allergic reactions to the materials, and shattering of the fossa piece. Screw loosening is a complaint common to all of these devices.

Conspicuous by its absence at this meeting is discussion of the polymethylmethacrylate condylar head device, on the market since 1961 and, following the recall

of the Vitek devices in 1990, aggressively marketed. Compelling evidence of the safety and efficacy of this device was not presented at the May, 1999 meeting. The PMMA shreds, leaving a nail-like projection to abrade against the metal fossa, which can then shatter. It is apparent that a PMA for this device has not been submitted by the manufacturer and it is no longer being marketed. Where does this leave the patients who have been implanted with this device? If it is found to be unsafe, shouldn't the FDA initiate appropriate action, such as a recall, alert or warning?

The most troubling information revealed at the 1999 panel meeting was that the manufacturer received 361 MDR reports and determined that only 4 were device related and reportable to the FDA. He blamed the remaining reports on the patients and the surgeons. This is a chilling reminder to us of Dr. Charles Homsey's defense of the Vitek devices -- he blamed the patients and the surgeons for the failures.

Upon hearing about the number of failures, we have to ask who has the responsibility for determining the cause of failures of TMJ Implants, Inc. devices? Is it the manufacturer, someone within the company? Is it an independent monitor? Does the FDA agree with the company's definition of device failure? When the FDA learned that

there had been 361 failures, did the agency investigate the reports? If they found the company responsible for the majority of failures, at what number does the FDA take action: If the device failures were due to surgeon errors, shouldn't the company be responsible for better surgeon training? If the failures are the patient's fault, are the patient selection criteria wrong? Was the diagnosis questionable? Was the use of the device for the patient's TMJ problem wrong? Or, is the problem that there are no uniform guidelines for aftercare for implant patients in the oral surgery and device community? Instead, there are different directions given to patients by different doctors.

We know that many surgeons never file MDR or Medwatch reports. They either don't know they should or they fail to comply, or their only criterion for failure is if the device breaks. One can only wonder how many more device failures exist that have never been reported Patients hesitate to complain about their device problems to their surgeons for fear of antagonizing them. If they call the manufacturer, they are told to speak to their surgeon. If they call the FDA, the agency is limited in what they can say and patients consider it an exercise in futility.

DR. HEFFEZ: Ms. Cowley, you have thirty seconds.

MS. COWLEY: In their frustration, patients who experience local and systemic problems related to their TMJ

air these problems online with each other and with us. It will be interesting to learn how many TMJ implant-related devices have failed since the 1999 meeting. We have heard from 34 patients with device failure.

This panel has weighty matters to deliberate. Your charge is to decide whether the manufacturer has met the scientific standards of safety and efficacy demanded of jaw devices. Thank you.

DR. HEFFEZ: For the record, could you please state if your attendance is supported by an association or company.

MS. COWLEY: TMJ Associates --

DR. HEFFEZ: Could you speak up?

MS. COWLEY: I am the president of TMJ Association and we will pay for my fee.

DR. HEFFEZ: Thank you. Ms. Cowley, I can invite you back to the podium to speak on behalf of Beverly Miller.

MS. COWLEY: Ms. Wilentz will.

MS. WILENTZ: My name is Joan Wilentz. I am a volunteer with the TMJ Association. I am on the Board of Directors. My expenses were not paid; I am local, and I have no financial interest.

DR. HEFFEZ: May I ask you just to speak more directly into the microphone? Thank you.

MS. WILENTZ: This is a letter from a TMJ implant

patient in Memphis, Tennessee, Beverly Miller. Dear Panel, everyone I know with a Christensen device has had either the head crack, the device break, screws come out. They have no end of surgeries, pain, suicidal thoughts and attempts, bankruptcy, family breakups, doctors no longer wanting to see the patients. They find disability very hard to come by and there have been no recalls. Ford and Firestone have worldwide recalls on the tires that have caused about 60 deaths. When are you going to have recalls on the TMJ implants that have caused hundreds of deaths and disabilities?

Beverly sent a photo that she would like the panel to look at. I will pass it around. This is the head of a TMJ implant where the screws came out; the shaft broke; the acrylic head broke through the patient's cheek. She developed two staphylococcal infections in her head, had to travel to another state to have surgery to have the implants removed. Her doctor refused to do further surgery to replace the implants after the staphylococcal infections had cleared up because she is now disabled and Medicare will not pay sufficient funds. She does not have the $10,000 cash to pay up front. Today she has no joints.

Please have all TMJ implants go through the strictest of testing and do not put others in this situation. One day it may be someone you love. Thank you,

Beverly Miller.

This is the picture of the patient with the protrusion of the joint implant through the skin. I will pass it around.

DR. HEFFEZ: Just for the record, you are here representing --

MS. WILENTZ: TMJ Association.

DR. HEFFEZ: The Association or Beverly Miller?

MS. WILENTZ: Well, I was asked by the Association to read the letter that came to the panel from Beverly.

MR. ULATOWSKI: Mr. Chair, I want to make it clear that each entity has one opportunity to speak, and the understanding that you spoke for the patient and not again for the Association, that is permitted but each entity has one shot.

DR. HEFFEZ: Thank you. I will invite Dr. Doran Ryan.

DR. RYAN: Good morning. I am Dr. Doran Ryan. I am not representing anyone but myself. My trip was paid for by myself, except I had breakfast paid for by TMJ Concepts. I had breakfast with them this morning.

I want to thank you for the opportunity to address this panel regarding the all-metal total joint prosthesis of TMJ Implants, Inc. I am an oral and maxillofacial surgeon in private practice, in Oshkosh, Wisconsin. I am also

president of the American Society of Temporomandibular Joint Surgeons. I have published numerous articles regarding the use and disuse of alloplastic implants in the temporomandibular joint. I have had the opportunity to do research on implants in animals both to find the results and the uses of these implants.

I really represent the oral maxillofacial surgeons who practiced during the Proplast Teflon era and has witnessed the pain and suffering of over 10,000 patients who had FDA approved Proplast Teflon placed in their temporomandibular joints. Many of those patients continued to suffer even after removal of those implants. In the early 1980s the FDA approved the Proplast Teflon as safe and effective for the use in the temporomandibular joint even though no independent testing of the product, nor any controlled clinical trials were established. The FDA relied on undocumented information from the company, that being Vitek.

In 1986, six years after the Proplast Teflon started to be used, I wrote a letter to Dr. Singleton of the FDA and to the editor of the Journal of the Oral Maxillofacial Surgery. I recommended the product not be used; all the patients be recalled and evaluated for removal of the implant. I had animal research to back up these recommendations. At least ten doctors wrote rebuttals to

Dr. Singleton and to the Journal. The implants were working for them and I was wrong. They claimed the problem was the technique and not the product.

Unfortunately, it was more than six years before the FDA acted on the recommendations, with the debate finally ending in 1992. The law suits continue today against the doctors. Patients continue to suffer, and the FDA did say they were sorry.

How quickly we forget. Now, in the year 2000 we are faced again with a novel approach to the reconstruction of the temporomandibular joint, that is the all-metal total joint. Is this product safe and effective? And, will it pass the test of time? I don't know that answer, but I don't think the FDA does either.

Here are the reasons why I question the approval of this product: There is no history of metal-to-metal temporomandibular joints. This is truly a new idea. Two articles were published, one in 1997 and the other in 1998, in a non-refereed book with the manufacturer as one of the co-authors. The mean follow-up time was 7.5 months and 26 months. Keep in mind, we didn't acknowledge Proplast Teflon failures for 8 years. That means we almost have 5 years of debt on this product. I have not seen any published controlled clinical studies with this product.

The only other joint in the body using metal-to-

metal total joints is the hip. It is a constrained joint, unlike the temporomandibular joint. The knee is closer in function and metal total joints are not used in the knee. The metal-to-metal hip joint failed in the '60s and '70s. Failure was attributed to poor control of sphericity, inadequate radial clearance via matched head and cup pairs, and unpredictable cobalt chrome molybdium microstructure secondary casting of the metal. This led to two and three-body wear. Excessive wear, metal fatigue and corrosion led to ultimate failure.

New guidelines, published by the American Society of Testing and Materials, include the following: The fossa and condyle need to be well matched and spherically controlled. As the difference in the radius increases, point contact occurs and a new product can lead to excessive wear. Cobalt chrome molybdium is more homogeneous and stronger than cast metals, which is the way this product is made. The fossa used in the system is cast metal, which is very thin, and combined with the point contact with the system has been shown to fracture.

The question of independent evaluation of this product must be answered. Who is independent, and does the testing follow the standards? I remember vividly being told by the manufacturer that acrylic on the condyle of the previous total joint of TMJ Incorporation didn't wear -- no

wear. We all know that that is not true. I was shown independent studies that demonstrated this fact. Yet, we know that the acrylic condyle did, and still does, wear.

Now the same company is offering up a new all-metal-to-metal total joint with, the best I can tell, five years of uncontrolled data. Have they followed the published guidelines of testing this material, and who is doing the testing?

DR. HEFFEZ: Dr. Ryan, you have thirty seconds.

DR. RYAN: I do not know those answers, but I know that you need to look very closely at that data. In conclusion, I hope I am wrong about this product and I hope that it does not fail but, please, don't give us another Proplast Teflon clone. Most importantly, please do not sentence more patients to a life of severe chronic pain and suffering because power and money is placed in front of science and research. I hope that this time if the product fails the FDA will take responsibility for their action and not just say, "I'm sorry," and leave the results of failure for others to manage. Thank you for your time and attention.

DR. HEFFEZ: Thank you. The next presenter invited to come to the podium is Michael Billingsley.

DR. BILLINGSLEY: Good morning, ladies and gentlemen. I am Dr. Mike Billingsley. I am a private

practice oral and maxillofacial surgeon from Colorado Springs, Colorado.

I am here to support the application --

DR. HEFFEZ: Could you please state your financial interest.

DR. BILLINGSLEY: Oh, yes. I am here to support the application for FDA approval for the Christensen Fossa-Eminence prosthesis manufactured by TMJ Implants, Incubation. My travel expenses were reimbursed by the company but I am not a stockholder and have no other financial interest in the company.

I represent a group of eight private practice oral and maxillofacial surgeons based in Colorado Springs, with satellite offices in Pueblo, Trinidad, Canyon City and Castle Rock. Our service area includes a population of nearly 750,000 in southern Colorado and northeastern Mexico. Our TMJ referrals come from a large base of dental practices and a number of physicians involved in chronic pain management.

Most patients referred to our group have an extensive history of non-surgical care by the time we see them, including medications, bite splints, physical therapy and psychological management. Some are under the care of orthodontic and prosthodontic specialists. In an average year, about 75 patients receive surgical evaluation in our

practice for their TMJ and dysfunction complaints. A thorough diagnostic protocol is observed, including extensive history and physical, response to prior treatment and x-rays and MRI evaluation.

Of this group, approximately 15-20 patients are identified each year as surgical candidates. Most are offered arthrocentesis if surgery is indicated, which has been a useful diagnostic and therapeutic aid for many patients. This is followed by at least 3-4 more months of non-surgical care with splints and physical therapy.

Out of this group, usually 8-10 in a year will still be found to have painful dysfunction and are offered a surgical arthrotomy. Now, the decision to operate requires the patient have continued painful dysfunction in spite of non-surgical or arthrocentesis care, with clinical and MRI evidence of internal disk arrangement and Wilkes categories III or higher.

There are patients who have failed non-surgical and arthrocentesis therapies in most cases, but the final determination for diskectomy and placement of a Fossa-Eminence prosthesis is reserved for the time of surgery, when the disk and associated tissues can be directly observed. If the disk is found to be anteriorly and medially displaced, perforated or tightly bound down with fibrous adhesions, and on repositioning of the disk is found

to be contracted with inadequate space between the anterior and posterior bands of the disk, this, to us, is a clear indication for disk removal and placement of a Fossa-Eminence prosthesis.

Using the stock templates, our doctors have always been able to achieve a good Fossa-Eminence fit, except in rare cases of severe bone destruction which requires a custom fossa prosthesis designed on the cadcam model. After selection of the proper size implant, the final Fossa-Eminence prosthesis is inserted. The dental occlusion and joint function are carefully checked, and the device is secured at the lateral aspect of the zygomatic base in the eminence with chrome cobalt screws. Following surgery, the patient is immediately placed on physical therapy to prevent early development of joint adhesions, and splint management is continued and the patient is carefully followed.

Our experience since 1991 with these devices includes over 80 Fossa-Eminence Prosthesis placements in 50 patients, and in this group 5 cases include total joint reconstruction with the condylar prosthesis, including 1 cadcam-base custom prosthesis. The total joint cases were in trauma, tumor and rheumatic arthritic situations. To date, no Fossa-Eminence Prosthesis only cases have required subsequent placement of the condylar prosthesis. Our success rate is over 90 percent based on our criteria of 35

mm of pain reduction from the usual level of 8 or higher on the VAS scale down to less than 2.

No major complications have been observed due to the device itself. In two cases, patients had implants removed by other surgeons but we were not provided with either the reason for explantation or any evidence of pathology related to the Fossa-Eminence Prosthesis.

DR. HEFFEZ: You have thirty seconds.

DR. BILLINGSLEY: One of the patients eventually proved to be emotionally unstable and has continued to seek multiple surgeries. Two patients, in the initial placements early on, required replacement with larger prostheses due to range of motion limitations, and have subsequently done well. One loose screw was removed under local anesthesia with no further problems. We have observed condylar surface remodeling in some cases on follow-up x-ray but no condylar resorption has been seen.

In conclusion, our experience with the Fossa-Eminence Prosthesis has been very rewarding. This device is extremely valuable in the surgical management of articular disk disorders and early degenerative disease.

DR. HEFFEZ: Your time is up.

DR. BILLINGSLEY: Thank you.

DR. HEFFEZ: I will invite the next speaker, Dr. Joseph Niamtu.

DR. NIAMTU: Good morning. My name is Dr. Joe Niamtu. I am a private practice oral maxillofacial surgeon, in Richmond, Virginia. I have no financial interest in the company. I have been asked by TMJ Implants to relate my experience with their fossa-eminence product, and I have been reimbursed for my expenses from Richmond to Washington.

Basically, there is no perfect device out there for temporomandibular joint disorders. If you look around this room on both sides, there are a lot of very eminent people here academically that have a lot of experience with this. As a practitioner in private practice looking for solutions, you can go around the country and you can talk to some of these very important people and you hear always do this; never do this -- there really is not one thing to do, and some things work real great in some people's hands and other things don't work well in other people's hands and there is a quandary.

We have a lot of patients. There are ten million patients that have TMJ problems and five percent of these patients will eventually be surgical candidates, and we don't have a lot of solutions; we don't have a lot of devices.

We have certainly learned lessons in the past from the Teflon Proplast, and there have been mistakes. But, basically, I want to just relate, firstly, my experience in

the private practice trenches using the fossa-eminence system, not the total joint; not the condyle but the fossa-eminence. I have placed about a hundred of these and, basically, I have been in practice for almost twenty years and I have counted about fifteen materials that I have put in the joint because at any given point in time that was something that was purported as good, or the next best thing, or what was going to help patients, and it has been a confusing situation.

I can only say that about a decade ago I was told by some of my friends that were using the fossa-eminence system that it was a viable alternative, and they were seeing good results in their patients. And, I started using this. The first one I put in was in about 1991. This patient is doing well. I can't say that none of these patients has ever had problems because there are a lot of variables when you put anything in or operate on any patient.

As a surgeon, when you choose to operate on somebody, anybody who is honest will admit that they have done possibly the wrong operation; they have chosen the wrong patient; they have not put the device in correctly. In my home town, I say, you know, I have had good experience with this. There are other surgeons who have used this product and they haven't had good experience. I think a lot

of it has to do with the learning curve and putting it in right, just like any device.

But when patients come to you, and if you see a lot of TMJ patients, by the time they get to you as a surgeon they are at the end of their rope. They are at their wits end. They have these horror stories. Some of these people want to kill themselves and, you know, they look you in the eye and they say, "what can you do for me? How can you help me?" And, there are just not a lot of alternatives.

I have used this fossa-eminence system. I have had good results with it. It has been an alternative. These patients have been able to open and close. It has helped their pain. Nobody is going to get cured. These people aren't going to get cured. They are going to have problems all their life because that is the nature of TMJ problems. But, I have not had to take these out. I have taken a few out and some of those may have been my fault. I may have technically not done it right and I may have put the wrong joint in the wrong patient -- the wrong eminence, but basically I have never had a loose screw from this fossa. I have never had a failure because of material. I have gone back and had to open up these joints to clean them out from time to time. I have never seen any significant resorption, and I have not seen significant condylar

resorption that some people state that they have seen.

Basically, in my hands this has worked well and it has been a good alternative, but I will tell you that for the last year and a half I have been kind of stonewalled because I have patients that I can't offer this to, and I would ask you to consider seriously about putting the fossa-eminence back on the market. I basically have people waiting because I don't really know what to do.

Again, I think a lot of it boils down to what works well in your hands as a surgeon, and probably you could bring fifty people in here and talk about something, whether it was cartilage or repositioning of the disk, or this joint or that joint and, you know, it may work well in their hands and it may really serve their patient population without any bad situations. Basically, I just want to relate to you that, by and large -- and I try to follow my patients very closely, they have had good experiences with this and, obviously, I wouldn't still be using it if I didn't have good experiences. Again, it is really important and I don't think anybody that can come up to this microphone that operates on people can say that everything always works well and they don't have problems because this is a confusing disease process.

If you look at the National Institute of Health Technical Assessment Conference data, there are a lot of

people out there with TMJ problems. We have all learned that you don't operate on people unless they have significant joint pathology, but there are a lot of people that come to me and other oral surgeons and they do have significant joint pathology, and what are our choices? You can't just tell these people -- you know, some people you can just tell them, "hey, if you just wait twenty years it's going to go away," but there are people -- like you heard today, their jobs are affected; their marriages are affected; their whole life is affected by this chronic pain and I think that I have been able to help a considerable population of these patients by using this device. So, I am just here to say that that has been my experience. I have not seen these negative effects that I have heard today, and this patient population has done well with this device. Thank you.

DR. HEFFEZ: Thank you. The next speaker invited is James Bergeron.

MR. BERGERON: My name is James Bergeron. I have no financial interest in the company. I have no support from them.

I want to thank you for giving me the opportunity to present before you on the review of the premarket approval application of the TMJ Fossa-Eminence Prosthesis, manufactured by TMJ Implants, Inc., by the Food and Drug

Administration.

My name is James Bergeron and I am the legislative director for Congressman Tom Tancredo. Congressman Tancredo represents the sixth congressional district of Colorado, which includes the southern and western suburbs of Denver, including Golden, Colorado, the headquarters of TMJ Implants. All of the current employees of TMJ Implants are constituents of the Congressman, and most of the employees who have been laid off by the company since this lurid tale began, more than a year ago, are constituents as well.

Now, the Congressman apologizes for the fact that he cannot be in attendance today because of legislative business on the floor. He, nonetheless, has taken an active interest and an active role in monitoring the progress of TMJ's implants application.

On numerous occasions he has met with Dr. Christensen, president of TMJ Implants, to find out information about the approval of the partial and total joint, and has personally talked to Commissioner Jane Henney and to members of the agency about the status of the company's applications. Congressman Tancredo has also been in contact with the House Commerce Subcommittee on Oversight which has sole jurisdiction over the FDA and issues relating to abuse and the internal operations of the agency.

Specifically, the Congressman has been closely

following this case since our office's first contact with Dr. Christensen and TMJ Implants in May of 1999. Incidentally, it was at this time that a meeting of the FDA's Dental Products Panel was held to review the company's PMA, and recommended approval of the PMA by a 9-0 vote. However, in spite of this action, it has not been lost on the Congressman that TMJ Implants finds itself in roughly the same spot today due to the actions or inactions of the agency. As such, I want to not only express Congressman Tancredo's support for the approval of TMJ Implants' partial PMA -- that is, after all, why we are here, and his desire that the Dental Products Panel approve the PMA much the same as it did in the 1990 panel, but also to express his concerns publicly about the process, and public health issues which accompany this application.

First and foremost, it is the Congressman's hope that the advisory panel will keep an open mind and listen carefully to the data that the company is presenting for the partial, for it meets the standard for reasonable assumptions for safety and effectiveness.

Next, the Congressman believes that the process has gone awry, and is concerned about the public health with the partial joint being withdrawn from the market.

On the process, I am sure you will hear the problems that the company has experienced from those after

me. It is no secret from all involved that there have been significant questions raised about the process, the sluggish pace of the review of the engineering data for both the total and partial joint and, more importantly, the constant moving of the goal posts during the review of both PMAs.

I sincerely believe that most of the frustration that has been expressed here could have been avoided had everyone sat down and laid everything out on the table in the spirit of what was fought for under the FDA Modernization Act. Unfortunately, the agency has been unwilling to do so, and it seems like these problems will continue into the foreseeable future. Thus, I will raise a question that others will raise as well as to why a new panel was needed. The May 1990 panel knew exactly what it was voting for. In fact, the panel was specifically told that it was voting whether to approve the PMA before it.

Now the public health concerns -- it appears that in an effort to address safety, and I am told that in this case the bar has been raised to a level significantly out of the ordinary, well beyond the statutory standard of reasonable assurance of safety and effectiveness. Because of this, the agency has done nothing more than cause harm to patients. It has failed to address the needs of the special patient population that is now suffering from the disorder and logically can be remedied without waiting until

degeneration of the total joint calling for irreversible surgery. Based upon history and data provided by the company, the device, which has a thirty-year clinical history, should not have been removed from the market. The fact is that the safety concerns are suspect and a health hazard has been created by the removal of the partial joint from the market.

You should know that the FDA, in August of 1998, made a finding of public health necessary for this partial device and, mysteriously, nine months later threatened denial of the company's PMA unless the partial was withdrawn from the market and in spite of receipt of significant additional data supporting FDA's own findings.

Over the last year and a half, our office has received numerous letters from physicians all across the country, from the Mayo Clinic to the University of Maryland, each relating to us the benefits of the partial joint and the fact that the partial and total joint results in immediate and dramatic decrease in pain, an increase in range of motion and increased function. Surely, the thoughts of these esteemed surgeons cannot be ignored, cannot be swept under the table.

The Congressman is concerned about what has happened here for this device is not available to clinicians that have made it clear that it is helpful. All of this

calls into question the integrity of the agency, something that the Congressman finds very disturbing.

Dr. Christensen is a true professional and a pioneer in his field and holder of the first patents. His implants are widely acceptable as effective and safe throughout the dental and surgery community. Indeed, several of my constituents have literally had their lives changed by the procedure. Congressman Tancredo is convinced that the work of the TMJ is based on solid scientific principles, and removal of the implants from the market has been, and continues to be, erroneous, contrary to the agency's earlier findings and the standard that should be applied. This has been devastating to thousands of people in the general public. This disaster must be remedied as soon as possible. Thank you.

DR. HEFFEZ: Thank you. At this time, I would like to ask if there are any other speakers who didn't sign in or signed in, in a delayed fashion and would like to present? No response from the floor.

At this time, I will ask panel members if they have any specific questions they would like to direct to one of the presenters. State your name.

DR. BERTRAND: I am Peter Bertrand, from the Navy. For the gentleman from Richmond, I was curious about your patient selection. Are these patients with fully

degenerated joints, or are these patients with internal derangements who have not responded to so-called conservative therapy?

DR. HEFFEZ: Please restate your name.

DR. NIAMTU: Dr. Joe Niamtu, private practice oral maxillofacial surgery, Richmond, Virginia. Basically, I think the standard of care that exist for temporomandibular joint disorders -- I think anybody who treats TMJ patients has a responsibility, before you lay a scalpel on a joint, to make sure that you have done everything for that patient because of what can happen from surgery -- any surgery. Basically, you know, most of the time by the time the patients get to many oral maxillofacial surgeons like myself, they have gone through all the conservative therapy with their primary treating physician and/or dentist.

I believe what you are asking me is what pathology I am looking for, or am I just using internal derangement. Internal derangement means a lot of different things to a lot of different people. When I explain it to patients I tell them that the innards of their joint are just not working in harmony; they are not working well. And, you can argue all day about what it is and what it isn't but, to finally answer your question, basically I look for the clinical signs. Most of the patients that I am operating on require a diskectomy. The far majority of them either have

significant perforations, or very significant areas of thinning that will eventually be a perforation, of the disk is just very hypertrophic and in some cases hypoplastic. These people open and close and it sounds like they have gravel in their joint. I mean, to me, this has been a pretty consistent clinical sign. When they open and close, it kind of gives you goose bumps -- "I'm glad my jaw doesn't hurt like that."

One of the big indicators I think is the position of the disk on MRI, although we all know that that is not a sole indicator but certainly these other clinical symptoms, this type of pain, limited opening, the crepitus and joint noise, and displaced disk or perforated disk -- all these things add up.

I think the biggest mistake a surgeon can make is just operate on somebody because the patient wants an operation or because nothing else works. I think people who do TMJ surgery -- you know, you come to a point where you learn who not to operate on and that is a significant thing. So, I think the presence of demonstrable pathology clinically and on imaging studies, and/or from previous invasive procedures like arthroscopy. Sometimes you will look in a joint and it is just beat up badly. So, this is what I use personally to make my decision, and I can honestly say that these people have been marched through a

progressive cascade of conservative treatments before becoming surgical candidates.

DR. HEFFEZ: Thank you.

DR. NIAMTU: Did I answer your question?

DR. BERTRAND: For the most part. Do you ever anesthetize the joint before you do your surgery to verify, other than the patient's opinion, that it is actually the pain source?

DR. NIAMTU: Yes, diagnostic blocking is a significant part of our situation. Again, I think most surgeons look for an excuse not to operate on somebody. I really do because, you know, you can really help somebody and you can open a can of worms. On almost all of these patients we will do arthrocentesis, usually in the office where we will use Marcaine to anesthetize this joint. We will place two needles in to rinse out this joint, and we will frequently put some type of corticosteroid in there. You know, doing the diagnostic block -- for the people who are non-clinicians here, one of the hardest things for a surgeon is to understand is this a muscle problem, is it a neurologic problem, or is it actually a joint problem. That is the confusing diagnosis here. I think that this has brought light to this situation. I don't think it is a hundred percent effective but I certainly think it gives you information on which to choose to operate or not operate.

DR. BERTRAND: Thank you.

DR. HEFFEZ: Any other questions from the panel?

DR. STEPHENS: I am Willie Stephens. I have a question I would like to pose to Dr. Ryan. I was wondering if you might speak for a moment about your thoughts about treating patients who have failed previous alloplastic surgery, and whether you have concerns about putting another prosthesis in that has a plastic wear debris.

DR. RYAN: Well, as we know and it has been published, after two and a half surgeries or two to three surgeries, most of these patients are going to fail any procedure we do. It is unfortunate that we don't have a better way to treat those patients. So, the patient who has had multiple surgeries many times have central pain. They really don't have peripheral pain that you can operate on. So, those patients are essentially chronic pain patients from that moment on.

What we try to do on those patients is reestablish function for that patient. Essentially there are two components we have to deal with, one is pain and one is function. Many times we cannot help their pain because it is now central pain and has to be treated medically. So, now we have to deal with the functional component of their problem, which is getting back to where they can at least chew and talk normally. In that case, we need some type of

alloplastic material in order to treat these patients.

Patients who have had multiple surgeries end up with very poor blood supply to the joint. So, autogenous material or natural tissues don't heal well in that joint. So, we need some type of alloplastic material. I think the thing that we need to look at is what is the best material to put in that joint that will cause the least wear debris -- everything is going to wear that we put in the joint. What material can we put in there that will cause the least amount of wear debris? Of that wear debris, which one of those particles that are produced will cause the least amount of reaction in the body?

So, I certainly think there is a place for an alloplastic material in the joint, but we certainly need one that has very little wear debris and one that does not cause further damage after it does wear. The problem in the past has been that we have not come across that. Acrylic in the past has been shown to be a problem in the hip joint, and that is a concern. Metalosis is certainly a problem, and you put metal-on-metal and you are going to end up with some problems because it wears, and it wears down fairly rapidly if it has point contact. So, I hope that answers your question.

DR. STEPHENS: If you have to do a joint replacement in a patient with a failed Vitek now, what would

you use at this point?

DR. RYAN: I am using TMJ total joint prosthesis which, as you know, is high molecular polyethylene and metal condyle against that, similar to the other joints in the body.

DR. HEFFEZ: Dr. Patters?

DR. PATTERS: Mark Patters. A question for Dr. Ryan and perhaps any of the other surgeons that spoke. I perceive that the patients and their representatives are implying that patients who are not successful lose confidence in their surgeon; lose confidence in the system; and are lost to follow-up and therefore, the success data is skewed because those patients returning for follow-up are happy and those are not returning are very unhappy. What is your personal experience and would you agree that that is a concern?

DR. HEFFEZ: State your name, Dr. Ryan.

DR. RYAN: Yes, I am Dr. Doran Ryan, from Oshkosh, private practitioner. I think that is probably true. I think what happens is there is frustration on both sides. The patients become frustrated with the fact that they still have pain and still have trouble with function, and the surgeon who placed the implants becomes very frustrated because the patient has not done well also. So, at some point that bond is broken between the surgeon and the

patient, and the patient wanders off to look for some other source of help. That has happened to me. I have patients that have wandered off, and I think I try to treat my patients very well but there is a certain frustration that everyone develops and, therefore, that bond is broken. They do. Patients do wander off and for that reason it is very difficult to track these patients and find out exactly the success rate, and we have proven that over and over again when we have looked in the literature and we find that in the temporomandibular joint everything had a 90 percent success rate, yet, we know that is not a fact. As time went on, we found out that many of those procedures had much less than that, sometimes less than 50 percent. So, they do get lost to follow-up for that reason.

DR. BILLINGSLEY: I would like to address one point, if I may.

DR. HEFFEZ: Restate your name in the microphone.

DR. BILLINGSLEY: Dr. Mike Billingsley, Colorado Springs, private practice of oral maxillofacial surgery. Our experience with Proplast Teflon patients has been limited but we have about a dozen patients in our follow-up group who had Vitek implants at one time. We did see some destructive changes in these patients, and followed them and recommended that they be removed, and we did replace them, all but one who refuses surgery, with the Fossa-Eminence

Prosthesis and they have uniformly done well without further decline of their condyles.

One thing that is extremely important is proper debridement of the joint in that situation because any particles left will continue to propagate the giant cell reaction against the particles of the Teflon. So, we think not every joint that needs to be opened that has a disk removed needs a total joint. This is an extremely expensive undertaking and fraught with many hazards, much less predictable, and in most cases it can be managed with the Fossa-Eminence Prosthesis.

DR. PATTERS: Thank you.

DR. COCHRAN: David Cochran. I would like to know from the physicians that have spoken what the percentage -- realizing that this is a cascade for many of these patients to get to the point they are at, what is the percentage of patients that you actually operate that have a condyle that is still intact enough to not use a total joint replacement and only the fossa?

DR. HEFFEZ: Specifically who are you addressing the question to?

DR. COCHRAN: Any of the oral maxillofacial surgeons who have spoken.

DR. HEFFEZ: So, Dr. Niamtu is the closest.

DR. NIAMTU: Dr. Joe Niamtu, Richmond, Virginia.

Can I answer the second half of his question or just the question that is on the floor?

DR. HEFFEZ: Answer the question on the floor, please.

DR. NIAMTU: Okay. Basically, what percentage of these joints have condylar damage? In my experience, very few of them. This is mostly for a disk problem. As I stated earlier, I can't say that none of these joints don't have some arthritic change on the condyle or an occasional osteophyte but, by and large, the vast majority of these that I have placed have been for a perceived situation with the disk. You know, the eternal question is when you get in that joint, what are you going to do with this disk? There are people today that will sit there and tell you that you can fix a hole in a disk, and orthopedic surgeons who will tell you that you can't do that because there is no vascularity. But right now we have well-known people fixing holes in disks. We have people that reposition disks, and there are people that still do it and say that they get good results but we know from the experience in the '70s that it didn't appear to work across the board.

So, to answer your question, when I get in that joint I am usually expecting to find a significant disk problem and the diskectomy or meniscectomy, taking that disk out, has worked well in my hands. The question again is do

you put something in there; do you not put something in there? And, the condyle is usually in good shape, and I have had better experience putting something in there, and that something is the fossa. If the condyle is in very bad shape, then possibly you do need a total joint.

DR. HEFFEZ: Thank you.

DR. BILLINGSLEY: Dr. Mike Billingsley, Colorado Springs. In terms of the numbers that you asked about, in our series of 80 implants, only 5 of those have required the total joint, and they were not generally related to disk disease; they were related to rheumatoid arthritic problems, sequelae of trauma and tumors in 2 cases.

DR. RYAN: Doran Ryan. I think we do total joints only as a last resort. So, we don't want to replace the condyle if we don't have to. I think in the case of ankylosis or severe rheumatoid arthritis a total joint is indicated but, short of that, I think we need to try to do something other than replacing the total joint itself.

DR. HEWLETT: I am Edmond Hewlett. I have a question for Dr. Billingsley. Dr. Billingsley, you indicated that in the 80 or so fossa-eminence implants that you placed you have observed some cases of condylar remodeling without condylar degradation or deterioration. I believe that is what you indicated. I am curious what criteria you are using to distinguish one instance from the

other, and also what is the longest time span that you have had to observe these cases?

DR. BILLINGSLEY: Dr. Mike Billingsley, Colorado Springs. The longest time span is nine years in our practice. Most of these joints we don't have to reopen. We have only reopened two or three and, at that point where the fossa has been in place for, I think, at least two you ears in each case we went back in. When we first started doing these fossa-eminence prostheses there was some controversy about whether or not to leave a healthy appearing disk in place. In a couple of places we left the disk in place with the fossa above it in the sphere joint compartment and we end up having to go back because of decreased range of motion in these patients and removing the disk. The patients subsequently did fine. The observation of the condyle at that point was that it was smooth. It had some eburnation with remodeling surface changes, but no cortical collapse; no sub-condylar necrosis.

I think it is very important in these cases to identify whether there is any evidence of avascular necrosis in the head of the condyle at the time that you make the decision to do this. If you have evidence on MRI or other means that there is avascular necrosis, you are probably looking for trouble and you may eventually have to replace the condyle at that point. But we have not generally seen

anything like that in the use of these fossas.

DR. BERTRAND: Dr. Billingsley, I am Peter Bertrand and I have another question for you, Dr. Billingsley. When you are screening patients for a surgical procedure, does the role of an SSSRI have any impact on your decision tree in deciding to do surgery, and how do you assess whether parafunction is still existing in that patient?

DR. BILLINGSLEY: We try to treat our patients with a team approach. We think it is wrong for patients to be shuttled from non-surgical care to surgical care and then not followed up. So, we insist on good control of parafunctional habits under the care of a non-surgical practitioner -- good splint therapy, physical therapy, management of the medications by a physiatrist, a physical medicine specialist. We try to sole-source the medication. All of those things are part of our team approach -- psychological evaluation and management if necessary.

So, if I understand your question, we think it is extremely important to manage the occlusion in these patients. In terms of parafunctional habits, we think that it is very difficult to control in some cases. We think most of the trauma to the disk apparatus and the condyle are probably related to this phenomenon than any other factor.

DR. BERTRAND: So, the decision tree is based on

the collateral providers that you work with and whether the parafunction is judged to be under control or not.

DR. BILLINGSLEY: And a sufficiently painful dysfunction and a positive clinical and imaging assessment.

DR. BERTRAND: And, do you have any data on the percentage of your patients that may be taking a selective serotonin reuptake inhibitor while they are having symptoms?

DR. BILLINGSLEY: It is very small. That is not used very much in our community. The physical medicine doctors do not use tricyclics to any great extent. I can recall three or four patients.

DR. BERTRAND: Thank you.

DR. HEFFEZ: Any further questions from the panel?

DR. BURTON: This can go to any of the surgeons. I would like to know what percentage of your patients come back on follow-up. There seems to be a very strong question about the number of people who have long-term follow-up and why they are lost to follow-up, and how long after surgery is their care covered under, let's say, a global fee or do they pay for follow-up, and are we losing a large number of patients, particularly the dissatisfied patients, because they have to pay for follow-up care? Not asking about their financial policies, but for non-study related patients, what are their financial costs?

DR. BILLINGSLEY: Dr. Billingsley again. This is

a problem with all of these patients. It depends on the state that you are practicing in. For example, last time I checked there were about 19 states that have a right to treatment law or regulation within the state, and those that don't are poorly covered by insurance, for the most part, in my experience. At least in my state that is the case. This joint seems to be excluded from the realm of right to treatment in comparison to other joints in the body. We think that is a horrible disservice to the patients.

In terms of losing patients to follow-up, it is difficult to follow these patients. We live in a mobile society. I spent twenty years in the military and I moved thirteen times, and I don't think that is so unusual anymore. We have patients, I would say, in our community that move -- I would say the mean is probably every five years. In our area we have a high tech base --

DR. BURTON: I am sorry, my real question revolves around the fact are those patients, let's say, three months, six months a year after surgery -- do they have fees for postoperative visits in your practice?

DR. BILLINGSLEY: My group has never charged for follow-up evaluation.

DR. BURTON: So, if a patient came one or two years later, or three years later, they would not then again be charged an examination fee. Obviously, there might be

radiographs and things like that which is a separate issue, but I am talking about a professional fee for follow-up.

DR. BILLINGSLEY: We have not charged that in our practice. We want to see these patients and we try not to discourage them.

DR. BURTON: Thank you.

DR. RYAN: Dr. Ryan again. Dr. Burton, most insurance companies have a global fee which covers ninety days post surgery. So, those patients are seen for free during that ninety-day period. I think all oral surgeons try to get their patients back. That is extremely difficult to do. I think most oral surgeons do charge a fee for follow-up evaluation. It would be foolish not to. I mean, that is how we make a living. Certainly, I am sure we make exceptions for patients who don't have insurance, and try to follow those patients, but I still believe that there is a high percentage of patients that are not followed long-term. We saw that in the Proplast Teflon when we went back to see what happened to those patients. There are still patients out there that haven't been contacted. So, we know these patients aren't followed that well, and that is certainly a concern and it is hard to put together a controlled study of patients because the follow-up is very difficult to do, again, because of the mobility already mentioned and the fact that cost does get in the way.

DR. HEFFEZ: Dr. Bertrand?

DR. BERTRAND: I have a question for Terrie Cowley, please.

MS. COWLEY: Yes?

DR. HEFFEZ: State your name, please.

MS. COWLEY: Terrie Cowley.

DR. BERTRAND: You mentioned that since the last panel meeting 34 patients with implants have come to your awareness with the TMJ Association. Do you have any way of verifying what type of implants those patients had received, and which company produced those implants?

MS. COWLEY: These were all implants produced by Christensen, TMJ Implants, Inc.

DR. BERTRAND: And how was that verified?

MS. COWLEY: We can't verify. We cannot have a registry that should be in existence for TMJ Implant patients. What we have is almost a complaint system. A patient calls us, a patient e-mails us, a patient writes to us and tells us, I have this device, or I have a device made by this company, or I have a titanium device. And, in a conversation with the patient or in correspondence with try to find out more specifics about what they have. For the most part, we do have accurate information -- I had a fossa; I had an all-metal total joint -- you know, whatever. We have those broad statistics, not scientifically validated.

Some people send us their x-rays. Some people send us their medical records, probably just trying to have us help them find out what they have. But if you are asking right now for a breakdown, I don't have right now how many of the 34 were fossas. I believe I can have that by this afternoon for you.

DR. BERTRAND: If your group can identify the oral surgeon that placed the prosthesis and it happens to be associated with one company or another company, do the companies or the registries freely communicate with you or is there a problem with that type of communication?

MS. COWLEY: The companies do not freely communicate with us unless there is some benefit to that for them. We have a problem. We have TMJ Implants, Inc. out there; we have TMJ Concepts. TMJ Concepts happens to answer any phone call from any patient who calls them. We know that. The patients tell us, and they tell us what the company is telling them about their device. They shuffle them over to their web site. They appear to be a company that communicates with the patients. Obviously, in the last year TMJ Implants, Inc. has not had any communication with patients. The people who have asked us how to communicate with the company; who is the company; where are they located, and on an on -- we simply give them their address and phone numbers. We obviously frequently hear, and I

brought this out at the last Dental Product Panel meeting, these patients are always told you have to talk to your surgeon. They do not communicate with the patient who has had any type of complaint or even question. So, this is what I am hearing. Is there a database registry of patients in the companies? We sure hope so because obviously we, the patients, are going to have to take control of a situation where there is an incredible discrepancy between what the patients are living, what they are telling us and each other, what the doctors are telling the patients, what the manufacturers are telling the surgeons and the patients. So, until and unless we are able to collaborate in some manner with an implant registry that is mandatory, not voluntary, that has an independent monitor, this database into which patient, direct patient information is given -- unless we have that we can't trust anyone.

DR. BERTRAND: Thank you.

DR. HEFFEZ: Any other questions from the panel? As chair, I have one question to Dr. Ryan. Many of your comments addressed metal-on-metal. Could you tell us if you feel there are any indications for the fossa-eminence alloplastic replacement.

DR. RYAN: I have not used the fossa-eminence implant, mainly because I think there are other procedures that can be accomplished, short of putting an alloplast in

the joint, for the indications they have indicated for that particular product. So, I have really not used that implant myself. I think my concern with it is that you are putting bone against metal. You are rubbing bone against metal and that, to me, doesn't make a whole lot of sense. It seems to me that bone is going to wear down from a biological standpoint. I just think there are other procedures that can be used. Again, there is no other joint in the body that does hemiarthroplasties. That has pretty well failed in the past. Does that answer your question?

DR. HEFFEZ: Yes, thank you. Any further questions from the panel? At this time, we will take a 15-minute break. We will reconvene at 10:45 exactly.

[Brief recess]

DR. HEFFEZ: We will proceed to the next part of this meeting, which is the industry presentation. I would like to announce for you that the sponsor we are going to be hearing from is TMJ Implants, Inc. Today we are reviewing premarket approval application specifically for the TMJ Fossa-Eminence Prosthesis. Without further ado, I again need you to state your name for the record.

Industry Presentation

TMJ Fossa-Eminence Prosthesis

MR. COLE: Than you, Mr. Chairman. My name is Michael Cole. I am an advisor to the company, but this

morning I am functioning in the role of moderator for the company presentation.

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We have a lot of information to present in a relatively short period of time. So, without any further preamble, I would like to introduce to you Dr. Robert Christensen, the president of the company and the developer of the implant, who will describe the clinical situation he was confronted with in the early '60s that led him to the development of the device, and where he believes it fits in the regimen of treatment for the GMD patient.

DR. HEFFEZ: While we wait for him to come to the podium I will remind you, you have one hour for presentation. We are starting at 10:45.

DR. CHRISTENSEN: I am Dr. Bob Christensen. I am glad to be here again. I do have a financial interest in the company, in case anybody thought I didn't.

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Back in the 1950s I had done surgery on this joint, on the patients and so forth, and had done a great deal of surgery on fractures and what-have-you but also had done things such as meniscectomies and so forth for pain in this joint and some of the other things that some of the older gentlemen remember. Dr. Laskin, back here, I know he remembers it. But we did things that at the time seemed

right, and they did do some good.

But I began to realize that something was needed to be placed in that joint. It was not any big study of mine to get there. I was driving down the road and it really hit me how I could do this, and that was the genesis of that in the 1960's, forty years ago.

A few months after that I operated on the first patient. This patient had had the meniscectomy and condylectomy done by another surgeon in the State of California, and she had a fibro-osseous fusion of the condylar neck to the articular eminence. I knew I needed to put something in there. So, I developed and put in the fossa-eminence implant on that patient.

There was a lot of discussion at that time on was this a viable procedure or not, and one of the things that really helped me at that time -- the two doctors that did the hip surgery, Dr. Smith Peterson and Otto Alfrank in Dr. Willie Stephens hospital, up there in Massachusetts, wrote a letter in '64 and said this is a real contribution to the surgery of a degenerative joint problem, and he knew what I had done. He had seen my first article in the American Journal of Orthopedics in 1963.

I began to realize that this thing was very useful in replacing that disk. So, that is how I did it and I began to do it, and I almost never had to reoperate on these

patients. I had an extremely good fortune over many, many years with it. We keep much better tracking today than I did then, but I can tell you that I look back at that first surgery about twenty-five years later and, instead of losing bone off that condylar neck, she began to grow bone back around it, and I went ahead and took that ankylosis out and left the original plate in that was there twenty-five years before and put a condyle below it. Forty years later she is still functioning. We have many patients just like that.

And, for somebody to stand up here and say they don't know about hemiarthroplasty in a joint -- they just don't know what is going on because Otto Alfrank and Smith Peterson had done it in the hip; many of them have been done since that time and certainly the shoulder joint is one that is operated quite routinely that way. So, without saying more about it, I think our presentation will answer a lot of questions for you and I will step back for Mike Cole.

MR. COLE: Thank you, Dr. Christensen. The question has been raised is unnecessary surgery being performed? Has the applicant sufficiently identified a patient population for whom the use of this device is suitable? We will attempt to address that question in a number of presentations this morning, and we believe that in large measure the standard of care is a very important consideration here, as is the diagnosis of internal

derangement. To address those subjects, I would like to present to you Dr. Rick Alexander, from St. Luke's Roosevelt New York, New York. Dr. Alexander is a recognized authority on the standard of care, having lectured, written and testified on the subject numerous times as it relates specifically to the oral maxillofacial surgery. Dr. Alexander?

DR. ALEXANDER: Thank you, Mr. Cole and panel members. I do not have any financial interest in TMJ Implants, Inc., and the expenses for my trip here -- the payment of those was assisted by TMJ Implants, Inc.

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I am the director of the Division of Oral -- let me say something in the beginning, we are going to use this term, OMS, instead of oral and maxillofacial surgery. So, when you see that term, that is what we are talking about. I am the director of the Division of Oral and Maxillofacial surgery at St. Luke's Roosevelt Hospital Center, in New York. St. Luke's is a major New York City teaching hospital and a level I trauma center. I am here primarily out of my interest in patient care and appropriate residency training for oral and maxillofacial surgery residents.

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CDHR has raised the question of whether there is unnecessary surgery being routinely performed for TMJ

disorders. It has been estimated there are some ten million people out there that at some point in their life have some kind of temporomandibular disorder. Approximately five percent of these patients have potentially a surgical problem. If you look at that number and look at how many people have a problem out there, I can assure you that nowhere near five percent of ten million are getting operated on.

The other issue I think is if you look at the ten-year closed-claim liability losses by description of procedure for TMJ surgery, AAOMS national insurance company, which is the largest insurer of oral and maxillofacial surgeons -- and, again, you are going to see this term, AAOMS and that stands for American Association of Oral and Maxillofacial Surgeons. This is the largest insurer of people in our specialty. Their ten-year closed-claim liability loss by type of procedure is three percent for TMJ surgery. It is higher than that for almost every other thing that we do. It is higher, for instance, for infections; it is higher for fractures; it is higher for dental-facial deformities. It is three times higher for those things, between eight and ten percent. Of the major surgical procedures that we perform, this has the lowest liability loss and I submit to you that if this surgery was being performed unnecessarily and poorly those statistics

would be much higher.

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The other question that the CDHR has raised is whether internal derangement is a specific diagnosis. Internal derangement -- I think I can show you that it is a very specific diagnosis. First of all, internal derangement has to do with disorders of the disk or meniscus in that joint. Now, the disk or meniscus is an anatomic structure made up of soft tissue that is interposed between the head of the joint and the fossa or the socket. This disk derangement has been classified and staged by a number of authors -- Wilkes, Bronstein and Merrill McCain. Wilkes is probably the best known, and his classification divides the displacement and/or damage to the disk into five categories, early, early-intermediate, intermediate, intermediate-late and late. And, that is very specific in my mind. The other authors have done the same thing but as related to arthroscopy.

In addition to that, the 1995 AAOMS parameters of care list internal derangement as a specific diagnosis. It is interesting to note that the 1995 NIH Technology Assessment statement recognized this publication as being an authority at this time.

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The 1995 AAOMS parameters of care, what it

basically does is it presents accepted patient management strategies, in this case for TMJ surgery. It presents them for other types of surgery we do. Now, the standard of care is defined as what a reasonable and prudent oral maxillofacial surgeon would do under the conditions.

I submit to you that a reasonable and prudent oral maxillofacial surgeon is going to follow these accepted standards. I am familiar with a significant number of people in the United States that do a significant amount of joint surgery. I am familiar with their practices, and I can assure you that complying with the standard of care and these strategies is the norm.

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If you are going to follow the standard of care, the first thing you have to do is make a proper diagnosis. Now, this is really important because temporomandibular disorders are of two types. The first type is not a surgical problem and it is not joint disease. This is just something where the patient can have pain that gets referred to the joint. They may have dysfunction of the joint, but it is not coming from the joint.

In contrast, we have another group of patients that have TM disorders which are actual joint disease. This is just like the hip, the knee, all other joints. These patients are potential surgical problems. You have to

separate these patients out if you are going to perform surgery and do it appropriately.

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The TM disorders that are not surgical or not joint disease -- the most common of these is muscle spasm. Now, muscle spasm can refer pain to the joint. It can also keep the patient from opening wide. So, you can get dysfunction and you can get limited opening and pain from muscle spasm. That is not joint disease, and those patients aren't going to be surgical candidates.

Now, these are actual joint diseases, and despite what anybody will tell you, these are the same diseases that occur in every other joint in the body. It is nothing, you know, magic. Now, ankylosis, infection, general anomalies, tumors and trauma -- except for those top two, I submit to you that those are unquestionably surgical problems. Wearing a splint isn't going to help any of those people.

Internal derangement or disk disorders and arthritis in the early stages -- and, when we talk about arthritis, there are all kinds of types of arthritis; the type that affects this joint most often is osteoarthritis or degenerative joint disease, however you like to call it. In any event, these two conditions will sometimes, depending on their state, respond to non-surgical measures early on. As the disease process progresses, they are pretty refractory

to those non-surgical treatments.

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The way we decide whether we have a non-surgical versus a surgical disorder is through a comprehensive physical examination, and I think it goes without saying that if you think the patient has a neurological problem, they get a neurology consult. If you think they have diabetes, they get an internal medicine consult. That is how we are trained to work patients up, just like everybody else in medicine or dentistry. So, that goes without saying. If you think the patient has a psychological problem, they are going to get a psychiatric and psychologic consult.

The other thing we use is imaging. The gold standard for imaging right now is the MRI because with these other imaging methods you can't see soft tissue and the MRI shows soft tissue. Internal derangement is a disk or meniscus problem and it is soft tissue. And, before the advent of MRIs, I will agree with anybody who said that we don't understand what is going on with this joint. I will tell you that with MRIs in combination with arthroscopy where we can look into the joint, we do know what is going on in this joint.

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Again, these disorders right here, except for the

top two, are without question surgical, and internal derangement and arthritis can become surgical problems. For instance, internal derangement -- we have heard a lot this morning about that, and the Wilkes classification, as I pointed out earlier, is a classification that ranges from a very limited displaced and damaged disk to one that is very displaced and damaged. And, patients that fall into the category of III through V frequently end up being surgical problems. Patients with long-term internal derangement frequently develop degenerative joint disease, and frequently become a surgical problem.

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Now, as far as non-surgical treatments go, there are tons of them out there. The ones that you are probably going to see the most attention paid to are splints, medications, physical therapy, TENS. Obviously diets and a number of other things play a role.

The splint thing has received a huge amount of attention. I will address that again in a second. Medications -- the things that are used most commonly are anti-inflammatories. Physical therapy can either be performed by the patient or they can be referred to a physical therapist. Then, transcutaneous neurostimulation, it is questionable whether that is valuable or not but there are people that use it and it certainly doesn't do any

damage.

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Now, splints receive all kinds of attention. What I classically see is a patient that calls me up and says, "oh, I've got TMJ and I'm wearing a splint." Well, TMJ is not a disease. So, the first thing we have to find out is what is wrong with them. I already showed you how we determine that.

So, a lot of these patients get a splint, and I think what you need to understand about a splint is that the only thing it does is unload the joint. Okay? These disease processes, internal derangement and arthritis are caused by overloading of the joint. Somebody on the panel mentioned that earlier, parafunctional habits, chewing on, you know, bobby pins, fingernails, gritting your teeth, those are all things that overload the joint. A splint unloads that joint, but I will tell you what it doesn't do. If you have an anterior displaced disk and it is all plastered down from adhesions, wearing a splint is not going to recapture that disk. Wearing a splint is not going to make a hole in a disk repair itself.

So, there is a role for splints to play but I don't think wearing a splint indefinitely serves any useful purpose. So, then the question comes how long should non-invasive or conservative therapy go on? Well, I think it is

reasonable to say that if conservative therapy, splints, medications etc. haven't decreased the pain, increased the opening and gotten rid of noises in one to six months, they probably aren't going to in one to six years. So, this is an individual judgment that has to be made between the patient and the surgeon. I think most people tend to be in this range, one to six months. Some tend to be closer to one or closer to six. I tend to be in the middle.

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All right, when do you operate on these patients? Well, we are back to the AAOMS parameters of care. The AAOMS parameters of care say that surgical intervention for internal derangement or degenerative joint disease is indicated only when non-surgical therapy has been ineffective, and when pain and/or dysfunction is moderate to severe in nature.

I will submit to you that Wilkes Class III through V fit most of the time in this category, pain and/or dysfunction which is moderate to severe in nature. Surgery is not indicated for asymptomatic patients. Pretreatment therapeutic goals are determined individually for each patient. I just mentioned that the patient and the doctor have to decide how long they are going to proceed with non-surgical treatment if the patient can't open their mouth, has pain and noises.

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Back to the parameters of care again. Parameters of care list a number of acceptable procedures for the treatment of internal derangement or degenerative joint disease, the first of which is arthrocentesis, which is just washing out the joint. Patients that have an inflammatory process in the joint are going to have a bunch of byproducts of inflammation and this, not uncommonly, gets rid of those and helps the patient for some period of time.

Arthroscopy, you do the same thing but you can actually look into the joint. It is a scope with a camera on the end. We look up on a monitor or television screen and we can actually see what is going on. So, the argument that we don't know what is going on in this joint doesn't fly. Between MRIs and arthroscopy, we do know what is going on.

Another treatment that they have listed as acceptably is arthroplasty with or without grafts. That can include meniscectomy or removal of the disk. They also list grafts as acceptable, autogenous or alloplastic. Autogenous are ones that come from the body and alloplastic are not. I submit to you that TMJ Implants, Inc. is an alloplastic graft.

We heard a little earlier from one of the speakers that hemiarthroplasty is not performed in any other joint.

In St. Luke's Roosevelt Hospital Center at least two cases a week of hemiarthroplasty of the hip are performed by orthopedic surgeons, and they place metal-on-bone with that procedure.

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This is really important because I don't think anybody who hasn't seen and worked with these patients can make any kind of a judgment, and you have to see the actual patient. Again, the parameters of care say that the ultimate judgment regarding the appropriateness of any specific procedure must be made by the individual surgeons in light of the circumstances presented by each patient.

Now, I want you to understand one other thing if you don't get anything else out of this. TMJ surgery or joint surgery of the hip or the knee, or any other joint, is not a perfect procedure. If you have a problem with your knee and you go to the orthopedic surgeon and it hurts, and you can't move it and you have noise in it, he or she is not going to tell you that they are going to operate on that joint and it is going to be like before all this happened. It is the same with TMJ surgery. The goal is to decrease pain, increase range of motion, get rid of noises and, to that extent, if you look at statistics we are as good, or better, at doing that than the people who do hips, knees, shoulders, whatever. I thank you for your time.

MR. COLE: Thank you, Dr. Alexander. We would now like to turn to two very experienced surgeons, the first, Dr. Anthony Urbanek in private practice, in Nashville, Tennessee. Dr. Urbanek used the Fossa-Eminence Prosthesis when it was available as a pre-enactment device. He also participates in the ongoing prospective clinical investigation. We have asked Dr. Urbanek to describe to you how he applies these standards of care or how does he pick his patients, what result has he seen with the device, and describe to you any untoward events that he has experienced, particularly any effect on the natural condyle. Dr. Urbanek?

DR. URBANEK: Thank you very much, Mr. Cole.

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My name is Tony Urbanek. I am from Nashville, Tennessee. I am an oral and maxillofacial surgeon, and I have no financial connection with TMJ Implants, Inc. or any other implant company. TMJ Implants, Inc. did support my expenses for this trip from Nashville to Washington today.

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First, I would like to go through briefly what I believe are my credentials to speak before this very august panel, and very well-experienced people here this morning. I have a dental degree which I got from Indiana; medical degree I received from Vanderbilt; went through my surgical

training at Vanderbilt, and entered a Ph.D. program toward a Ph.D. in anatomy. At that point in time, I applied for and was given a grant to the NIH for study of intrauterine field surgery using a laser. This was in 1976 before almost anybody knew what a laser was. I bring that to your attention not to pat myself on the back but just to say that I am a scientist; I am not just an oral and maxillofacial surgeon who does surgery every day. But that is what I am very proud of doing, and that is what I do.

I have a lot of experience and, in 1981, after doing all of that training I decided, for various reasons, that I was going to come out into private practice and I wasn't going to be an academician. At that point in time, in 1981, I was confronted and needed to see many patients with temporomandibular joint complaints. Over a period of the next ten years, between 1981 and 1991, I tried and utilized all modalities of treatment that were available for these patients, conservative, non-surgical, surgical -- all varieties. If it was written about, I tried it.

What I found out during many, many, hundreds of patient experiences, many, many surgeries is that without exception, especially for the surgical patients, I did meniscectomies without reconstruction. I did meniscus reconstruction. I used all kinds of alloplasts and other types of implants, and I found that consistently within six

months or a year each and every one of those patients would return to my office and tell me that they had the symptoms that they originally came in with and the same complaints.

This was very disconcerting. It was very frustrating. As I believe was mentioned earlier, I was at the point where I had decided I just didn't want any more part of temporomandibular joint surgery. If there is anyone in the room who is concerned and worried about the use of alloplasts and the use of implants in temporomandibular joint surgery, it is me. Between 1983 and 1987 I placed 80 Proplast Teflon implants. I have now taken out 78 of them, and the two that are in, in the same patient, are in a good friend of mine and I can't convince her to get them out. I see her frequently and I will take them off for nothing. But I have experienced that problem. I have had to confront it and, believe me, I would be the last person to engage in any kind of activity that I did not believe was successful for my patients.

With my comments about my technical credentials, I would like to say that I am not representing myself at this point in time as a scientist. My experience -- 35 percent of my experience, 35 percent of my patients are represented in the study that TMJ Implant will present to you very briefly, and I let those facts speak for themselves. I don't speak to you as a clinical. But I speak to you today

because I represent my patients. I represent those 351 joints and 217 patients that I have done, and I represent these 14 patients, now 16 because there are two added to this list as of Wednesday, my last day in the office before I came here -- I represent these 16 patients who were unable to get the partial joint prosthesis for the past 6 months because it has been taken off the market by the FDA.

I am the one who has to explain to these patients why it is taken off the market. I had a conversation about eight months ago, maybe nine months, with Dr. Runner who asked my opinion -- this was on the telephone -- asked my opinion of my experience with this implant system in patients. I went through in great detail what I thought of it; what my experience was; my indications for putting it in; how I handle my patients; and exactly what I thought of it. I also asked her, I said, you know, this is a very good prosthesis. It has been on the market for 35 years. I have not had any significant problem with it. I would like to know why it is being reviewed again. I mean, I understood all of the problems in the review process and I wanted to know exactly why it has taken so long to get this thing approved.

I didn't get any direct answers, but what Dr. Runner did ask me is, she said, Dr. Urbanek, what would you think if, in the next couple of months, we took this

prosthesis off the market for a period of time while we reviewed it? Because, at that point in time, it was still on the market. And, I said, Dr. Runner, this is not a question you should ask of me. This is a question you should ask of my patients. I can tell you what my patients will say. My patients will say that they are having extreme pain and that they want relief.

Now, this lists 16 patients. It is available to you if you care to see it. I agree with everything that Dr. Alexander presented to you this morning as to how I select the patients, my criteria, the use of the American Association of Oral and Maxillofacial Surgeons criteria, but it is the patients I want to speak for.

Over the period of the last ten years, beginning in 1991, I began using the Christensen prosthesis very carefully at first -- very carefully at first. I did a patient. The patient came back in six months, doing well. The patient came back in a year, doing well. Well, I got a little bolder. I went and did another patient. Well, over the next ten-year period of time I found that with the Christensen prosthesis, without almost any exceptions, after six months, after a year, after two years and longer the patients would come back and respond that they are doing well. Their function was good. They could chew what they want. They were opening well and, most importantly, they

were out of pain. This is what I am confronted with daily, to deal with patients with pain, not for weeks or months but patients who have had five years, ten years, fifteen years, twenty years of constant, consistent pain and I am the last guy that they come to. They have already been to dentists. They have already been to neurosurgeons. They have been called crazy. They have been to psychiatrists. They have been on drugs. They have had surgery done on their sinuses. They have had surgery done on their nose. They have had all kinds of other surgeries and finally somebody, you know, pushes on their joint, the joint is tender and they say maybe you ought to go and see Dr. Urbanek.

I have a referral practice. My results are somewhat skewed because I don't see many patients who have Wilkes class I and class II temporomandibular joint problems. I see patients who have been around the block lots and lots, and they come from all over the State of Tennessee and beyond. The reason that I have accumulated this many patients is because it is successful. I will present with all sincerity to this panel do you think that I would be doing a procedure this many times and having patients coming back to me, saying, "I have pain; it doesn't work. I'm in the same shape I was in before."

Since 1991, I gradually began getting bolder and bolder using the prosthesis more and more. It is my

definite experience that it is a very, very successful prosthesis in the way that it handles patients' pain and in ability to open. I have not seen any patient go to fibrosis after the use of the prosthesis. I have been into approximately five joints two years or so, or more, after the prosthesis was placed, because of trauma. I have had several patients who have had accidents after the prosthesis was placed. The prosthesis was displaced and I had to go in and replace it, just literally take the loose one out, put the new one in and then they went along their way. But at that point in time I was able to see the condylar head. I was able to visualize the condyle when I went in. Visually, I have never seen any evidence of condylar degeneration of the mandible on a prosthesis that has been in anywhere between a year and five years.

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The patients' response goes back in my practice to 1991. I have a twenty-year experience, and utilized all types of treatment. My practice is a referral type of practice. I have used the indications from AAOMS. And, over that twenty-year period, it is my common, consistent action that after I do a maxillofacial case of any kind, after a year or so I ask the patient if they want to write a success story about what I did for them. I have accumulated, not only on temporomandibular joints but on all

kinds of facial surgery many, many success stories. I have before me, in my hands, ten of those success stories on patients who had done temporomandibular joint glenoid fossa implants over the past ten years, with the earliest one in this pile going back to 1994. If you care to read them, I have brought copies. I have a hundred more back in the office, if you would like to see some more.

But, I would like to read one, again, on behalf of my patients because that is who I am speaking for: For the past twenty years I have suffered with headaches, chronic neck pain, facial pain, earaches, toothaches, shoulder pain and clicking of the jaw. As my pain got worse, I began to mention it to different doctors. They all thought I had sinus problems. So, after a series of tests, medication and x-rays proved not to help it and the problem got worse, I went to an ear, nose and throat specialist. He said that he thought I had TMJ but he didn't think anything could be done. Then I checked with my dentist who gave me some jaw exercises to do which did not make any difference in my pain either. Then I remembered a friend who said that she had TMJ. I questioned her about the symptoms and she referred me to Dr. Urbanek. I had TMJ surgery and have not had one headache, period. All of the other pain is gone. Needless to say, I am thrilled and ever so thankful for my relief. I feel younger and alive again.

I have only read one to you but this is representative of what I am holding in my hand. It is also representative of the hundred I have in my office. I am not here to promote TMJ Implant, Inc. I am here as an advocate for my patients. I have found over the past ten years that there is a prosthesis that in my hands consistently works to the betterment of my patients.

You know, I take it as an insult that my results by some have been called anecdotal. You know, I want to make it clear that all of us -- everyone on the panel, everyone who is a professional in the room, and myself included -- our primary interest is in the treatment of patients. If we get lost in the science, which is important -- I am a scientist. I am the guy who did the earliest study on fetal surgery. But if lose point of the fact that we are treating patients and that is what we are here for, for their goodwill and to protect, then we are not doing our job.

Now, I also want to state that I have heard from others who preceded me negative comments. Dr. Ryan had negative comments. I want to say that he admitted in front of you he has never done a partial joint Christensen implant. I present only my experience in retort.

So in summary, I would like to ask the panel to carefully look at our presentation as to the effectiveness

and safety of the glenoid fossa Christensen partial insert, which I think is what our charge is here at this meeting. In fact, I know that is what our charge is at this meeting -- the partial prosthesis.

I would like you to look at the evidence presented, the scientific evidence presented. The scientific evidence that will be presented is very clear-cut. The scientific evidence are a part of in the study which I have entered as a participant in Christensen company backs up the science behind it. But I ask you most importantly to consider the patients who will benefit by having it available. When you make your decision at four o'clock or so, I ask you with all humility to approve or to make a recommendation, because I understand it is a recommendation panel, to make your recommendation for approval and, as human beings, add that we expect it to be approved. Thank you.

MR. COLE: Thank you, Dr. Urbanek. We need to move along now right to Dr. James Curry, in private practice in Colorado, who will talk about his selection criteria, results, and make some comments on the FDA review of a study that was submitted in the premarket approval application dealing with wear on the natural condyle. Dr. Curry?

DR. CURRY: Yes, I am Dr. James Curry. I have been doing temporomandibular joint surgery for upwards of

about thirty years, and I have had about a twelve-year experience with the Christensen devices.

[Slide]

I would just like to state up front that we use a very similar technique in making a diagnosis and treatment plan for patients who might be needing a hemiarthroplasty.

[Slide]

I would like to show you just a study of some patients that I did prior to the registry that TMJ Implants, Inc. was required to keep, beginning in 1993. I looked at patients that I had operated between 1988 and 1992. This study was subjected to statistical scrutiny and there is a significant decrease in the pain in this group of patients, 50 in this study.

[Slide]

We looked at opening in a similar group of patients, and it has already been commented on that we do have some problems getting all of these patients back. These patients were measured with a Therabite measuring device, and there is a significant increase in the patient's ability to open in this group of patients.

[Slide]

This group of patients then was compared with patients from the TMJ registry and patients from our ongoing prospective clinical trial. You can look at the numbers of

patients in these various studies, but the thing that I want you to really see is the amazing similarities in the beginning pain levels, the postoperative pain levels, the beginning opening levels and the postoperative opening levels.

[Slide]

There have been a number of questions raised at this meeting and at other times about what is the condylar response to the hemiarthroplasty in this joint, what is the bone response. We have heard some anecdotal remarks and no one seems to have any science on this. We follow our patients clinically and radiographically to make a determination whether or not the condyle has pathologically degenerated following our procedures.

[Slide]

This is an example, and I will show you two or three cases to typify what I have seen in my clinical practice and in my study. This is a stage IV internal derangement patient preoperatively, immediately postoperatively and 11 years, 9 months postoperatively. This is pretty typical of the patients that we see, and we generally follow our patients with Panorex. I don't charge my patients for coming back and I don't even charge most of them for their follow-up x-rays.

One criticism of the model fossa liner has been

that it obscures our ability to look at every detail of the condyle, but I submit to you that you can't see every detail of a condyle on a Panorex anyway. In this particular series you can see very clearly that there is very little, if any, pathological remodeling anyway.

[Slide]

Let's look at this slide. This is the opposite joint in the same patient. I submit to you that this one is obscured even a little bit more in all three views, but when we look at the clinical picture of a patient this long after surgery and their occlusion hasn't changed, and their pain level is practically nil, and they can eat almost anything they want and their maximal incisal opening is 42 mm -- you have to look at both the clinical as well as the radiographical to follow these patients along.

[Slide]

This is a stage III internal derangement. This is immediately postop, in 1989, and this is a 5 year, 1 month radiograph. There are no real changes between the two, but you can't see the actual edge of the condyle as the fossa liner obscures that a bit.

[Slide]

I decided sometime ago that to try and answer this question for myself and my patients I would do some CT scans on some of these patients where the condyle was not as

visible as it might be. This is a CT scan of that patient. This is 10 years, 1 month postop. Clinically she is doing as well as any patient that I have, and in the sagittal CT scan you can see a very nice cortical outline and a nice marrow space, and in the coronal view you also see that the condyle has not degenerated.

[Slide]

This is an example of a stage V internal derangement. This is a multiply operated joint patient. This is the presurgical Panorex. This is the immediate postsurgical Panorex -- no, 5 years, 1 month postop. Again, a little bit of distortion because you can't see through the metal fossa liner.

[Slide]

This is the opposite side of this same patient. Again, you can't see all of the condyle. So, we did a CT scan on this lady.

[Slide]

In the CT view you are able to see more of the condyle. This is the sagittal in three different levels. This is the coronal view, and there is no pathological condylar degeneration 9 years, 9 months postop.

[Slide]

This is the opposite side. This is the sagittal and the coronal view of the same patient.

[Slide]

I would like to submit to the panel that this is an example of a patient, and this is a tomogram of a joint in 1983. This patient went through standard conventional treatment for temporomandibular disorders and temporomandibular joint pain and dysfunction. Over the course of time, when she got to my office in 1991, there was absolutely no condyle there. This patient has never had an alloplast in this joint. This is the opposite joint.

What I am trying to explain to you as well is that you can see these kinds of pathological deteriorations radiographically even with a metal fossa liner in place.

[Slide]

You also begin to see clinical evidence of severe degenerative joint disease with open bite deformities, and that is the way this lady presented.

[Slide]

I would like to comment briefly on the idea that every TMJ patient must go through an exhaustive non-surgical treatment regimen. I think Dr. Alexander stated this very clearly. This is a 16-year old girl, fractured condyle, ankylosis. This patient doesn't need psychological care; this patient doesn't need splints. This patient needs surgery, and the surgery that we did -- rather than do a total joint, or rather than put some kind of a ribgraft in

here, we did a hemiarthroplasty. I submit to you that hemiarthroplasty is much, much better for some patients than subjecting patients to total joint procedures.

[Slide]

This is another example of a pathological condition. You can see the tumor. This is synovial chondromatosis. This patient needs an operation. So, this was done.

[Slide]

In conclusion, surgeons must exercise good medical judgment in deciding whether to place the partial joint. There is an abundance of clinical evidence to support the use of a partial joint replacement system in this joint. CDRH should not substitute its judgment for the years of clinical experience with this device. Thank you.

MR. COLE: Thank you, Dr. Curry. We are running out of time and we have two very important presentations to make so I would like to move right into the results of both the prospective clinical study and the registry data, which we believe demonstrate that we have identified the patient population and demonstrated that the device is safe and effective for use in that patient population. To make the presentation on the clinical results, Doug Albrecht, the manager of clinical affairs at TMJ.

MR. ALBRECHT: Hi.

[Slide]

Right now, we have two data sets of patients that we are going to report on. One is our prospective clinical study, for which you received all the data that we have collected so far in your packet. What I am going to present here today is data regarding the indications for use compiled from that data.

[Slide]

To date, we have 113 patients with a partial joint replacement enrolled in the clinical study, and 109 of those are evaluable at this point. There were 4 recently enrolled patients for whom the data has not been collected yet.

The demographics are typical for this population of partial joint replacement, and in this group of patients 75 percent of those patients have received stock implants.

[Slide]

Dr. Runner's question or statement that internal derangement was not a specific diagnosis was taken back to our investigators and we asked them, you know, can you give us some more specific information with regard to the diagnosis that was given. Originally they reported 81 percent of the patients enrolled with a partial joint had internal derangement.

Upon revisiting this with the investigators, we found that the majority of the patients still have a

diagnosis of internal derangement, with about one-third with perforation, two-thirds without perforation, and about ten percent with inflammatory arthritis. The majority of those patients in the inflammatory arthritis group also had a secondary diagnosis of internal derangement. Therefore, we are looking at about 85 percent of the patients with a diagnosis of internal derangement that did receive a partial joint replacement.

[Slide]

Again, as Dr. Urbanek and the other surgeons have alluded to today, these patients exhaust most non-surgical modalities when they are indicated for the patient, and these can be any of these listed on this slide.

[Slide]

When they have exhausted the non-surgical modalities, we have found in this clinical study that for 82 percent of the patients this is their first TMJ surgery, and the rest have had between one and six previous TMJ surgeries before receiving the prosthesis.

[Slide]

This graph is a graph of the pain reduction from the prospective study from those patients with internal derangement and with fibrosis and ankylosis. As you can see, they all start out with a pain level of 1-10, 10 being the most pain imaginable and zero being no pain at all.

They all start out at about a level of between 7 and 8 on this VAS scale, and within 3 months after surgery they have clinically significantly reduced their pain levels to about a 3 and this continues to go on for about 3 years post-implant.

[Slide]

The same is seen with the interincisal opening. Again, for those patients with internal derangements and fibrosis and ankylosis, they all begin about the same place, between 30-35 mm of opening, which is fairly acceptable for this group of patients. Immediately postop their opening does go down due to the postop complications, but then back up to about between 30-35 mm and this extends out to 3 years postop.

[Slide]

We have seen no unanticipated adverse device effects from this surgery. We have had one event that is related to catching of the joint, which may be attributed to the positioning of the implant by the surgeon, but everything else is associated with either surgical complications, disease progression or trauma.

[Slide]

We also track patients in our TMJ Implants registry. Upon registry, we ask physicians for historical information, as well as some diagnostic information but not

as detailed as the prospective study. In the TMJ registry we have collected pain and opening data on over 1300 patients since 1993. In order to track as many patients with as complete data sets as possible, we have isolated a cohort of 88 subjects which have complete data from preop all the way out to 3 years of implant duration. That population, as stated here, is typical of the partial joint population as shown with the prospective study.

[Slide]

Again, we ask the physicians to provide us with the Wilkes classification upon registration of the device after surgery. These are the definitions, as we have alluded to before in presentations.

[Slide]

Out of the 88 patients, the surgeons for 46 patients did report the Wilkes classification of class III or higher. We had no reports of I or II in this cohort group. Additionally, 50 out of the 88 patients reported surgical history, 36 percent of those having their first surgery at this point, and the remaining two-thirds of the patients had anywhere between 1-9 surgical procedures.

[Slide]

In looking at the cohort of 88 patients and the 46 that did report the Wilkes classification, we see the same pain levels, starting at about 8 on a VAS scale of 1-10.

Within a month after surgery the pain is clinically significantly reduced, and this continues on out to 3 years post-surgery.

[Slide]

We see the same information again with the interincisal opening for the same group in class III, class IV or class V Wilkes classification. They start out at about 30 mm postop and then improve out to 3 years implant duration.

[Slide]

As I said before, we do have data on over 1300 patients within the TMJ Implants registry. Out of those 1300, over 800 surgeons returned the Wilkes classifications for their patients, and this graph represents the cross-section of that population. Cross-section means that we don't have the same patients followed at every time period. Because of the ongoing follow-up, patients either have not met that follow-up period or have been lost to follow-up. However, the numbers are fairly significant within the three classes of class III, class IV or class V.

[Slide]

We do again see a significant decrease in pain within the first month of surgery and that continues out to almost five years in implant duration.

[Slide]

We see the same information with regard to the interincisal opening with the class III, IV and V, with again significant improvement in opening out to 5 years implant duration.

[Slide]

With regard to any adverse device effects within the registry cohort of 88 patients, we have seen no unanticipated adverse events for this group of patients, and 93 percent of these patients still have the original fossa-eminence implanted three years after surgery.

[Slide]

With the cross-section of the 1358 patients minus the cohort of 88 -- so, we have two separate populations, again, 93 percent still have their original prosthesis implanted after five years implant duration.

[Slide]

The big key here is reproducibility of the data. No matter how you cut the pie; no matter what population we have looked at, whether it is the prospective study, whether it is the registry or whether it is independent data from other surgeons, we see the same information time in, time out. Looking here at the prospective cross-section of the ongoing trial, I have also been able to isolate 21 patients in the prospective study with complete data through 2 years, as well as the registry cohort which is 88 patients out to 3

years, and we see the same information of a significant decrease in pain and that continues out long-term.

[Slide]

We see the same information from the same three groups of patients with regard to interincisal opening.

[Slide]

In conclusion, we believe that the Christensen partial joint replacement is effective for the indicated populations of internal derangement with and without perforation, and associated with inflammatory arthritis. These can be correlated to Wilkes class III, IV or V. We have shown that a small population of patients with fibrosis and ankylosis do improve with the implant, as well as patients that have failed previous TMJ surgery, either autograft or allograft.

[Slide]

Again, we believe that the device is safe for the indicated populations. The overwhelming majority still have the device implanted at least after three years after surgery and some out to five years. We have seen no unanticipated adverse device effects, and there is no evidence that has been presented that the device causes degeneration of the natural mandibular condyle. The clinical data do demonstrate that the metal-to-bone articulation will not cause degeneration to the natural

mandibular condyle. Thank you.

MR. COLE: Thank you, Doug. I know, Mr. Chairman, that we are virtually out of time. We have one more presentation that we waned to make in response to comments made by the Food and Drug Administration in its submission to the panel that, in fact, no engineering data on the partial had been submitted. I don't know if you want to take two minutes to do that. I would like to confirm that, in fact, the report that we prepared in response to that statement was distributed to the panel. If so, that might suffice in place of the testimony.

DR. HEFFEZ: You actually have three minutes left, if you can be concise.

MR. COLE: I would like to introduce you to Mr. Durnell, one of the fastest talkers in the company, who will now very quickly go through the data on the partial joint that was in the premarket approval application.

MR. DURNELL: Thank you.

[Slide]

Good morning. I am here to summarize the preclinical testing which has been submitted in the PMA. A small percentage of the testing submitted in the original PMA was pertinent to a total joint system. However, the majority of the testing is relevant to both a partial and a total joint system, and was conducted either on

representative material samples and devices or on the actual devices themselves.

The justification for use of all of these various testing configurations was explained in the appropriate sections of the PMA, and there were four distinct testing configurations. One, we used the material sample of cobalt chrome. This we used for the tensile property testing and corrosion testing.

The second configuration was cast cobalt chrome condylar prosthesis. This is made from the same material, utilizing the same processing as the Fossa-Eminence Prosthesis, and for that we tested the perpendicular and 3-point bend testing, and the biocompatibility testing was conducted using an extraction from a condylar prosthesis. Those include the systemic tox, cytotox, mutagenicity, irritation and intracutaneous reactivity.

The actual fossa device against a condylar prosthesis as a worst case scenario -- the is justification for this as a worst case is that, number one, it represents a single point contact which concentrates the forces and, two, this configuration is a hard alloplast on a hard alloplast. For these tests, the following tests -- contact area, contact stress -- all of our wear testing was done using this worst case -- physiologic fatigue and, in response to discussions with the panel and the Center, we